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- (74) Agents: BECKER, Philippe et al.; Cabinet Becker et Associés, 35, rue des Mathurins, F-75008 Paris (FR).
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- (71) Applicant (for all designated States except US): CYTHERIS [FR/FR]; 21, rue Aristide Briand, F-92170 Vanves (FR).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): MORRE, Michel, Christian [FR/FR]; 67, rue Nationale, F-92100 Boulogne Billancourt (FR). ASSOULINE, Brigitte [FR/FR]; 12/14, rue Sébastopol, F-92400 Courbevoie (FR). CORTEZ, Pierre [FR/FR]; 17, rue des Grands Augustins, F-75006 Paris (FR). GREGOIRE, Anne [FR/FR]; 1, rue des Morillons, F-7015 Paris (FR).
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(54) Title: IL-7 DRUG SUBSTANCE, COMPOSITION, PREPARATION AND USES

(57) Abstract: The present invention relates, generally, to the fields of immunology and molecular biology. The invention discloses, more particularly, new and improved interleukin-7 drug substances, corresponding specific immunoreactive antibodies, as well as compositions comprising the same, their preparation and uses. The invention also discloses methods to characterize the impurity profile of a r-hIL-7 drug substance used for therapeutic purpose, as well as optimized nucleotide sequences encoding mammalian IL-7, recombinant expression vectors and methods for preparing and purifying said polypeptides. The present invention stems from the unexpected discovery that the long term activity of recombinant IL-7 is mostly expressed by a specific conformer and that other conformers, potential product-related substances, product-related impurities, and process-related impurities, which would normally be included in the specification of the drug substance and/or drug product, although bioactive, should be strictly minimized because they are able to trigger an immune reaction against the desired IL-7 molecule.